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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/634,292	08/05/2003	Karen M. Haberstroh	3220-73239	7977

23643 7590 05/29/2007
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EXAMINER	
DAVIS, RUTH A	

ART UNIT	PAPER NUMBER
1651	

MAIL DATE	DELIVERY MODE
05/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/634,292	HABERSTROH ET AL.	
	Examiner	Art Unit	
	Ruth A. Davis	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) *21-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I, claims 1 - 20 in the reply filed on March 9, 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 21 – 32 are withdrawn from consideration as being drawn to non-elected subject matter. Claims 1 – 20 have been considered on the merits.

Specification

2. The abstract of the disclosure is objected to because the abstract must be a single paragraph. Correction is required. See MPEP § 608.01(b).

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on May 24, 2005 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner. However, the reference listed as "DU" on page 4 by Paul Weiss must include the full citation of the document. Specifically the source and date, including the publication year, must be provided.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1 – 5 and 10 – 16 and 18 – 20 are rejected under 35 U.S.C. 102(e) as being anticipated by Webster et al. (US 6270347 B1).

Applicant claims a nano-structured synthetic implant comprising a polymeric material having nano-sized surface features; wherein the features have one or more dimensions of 50nm – 1um; 100 nm – less about 1um; 50 – 100 nm; or 25 – 50nm. The polymeric material is biodegradable; selected from poly (lactic acid – glycolic acid), polyetherurethane or polycaprolactone. The implant further comprises an extracellular matrix component; from bladder smooth muscle; from proteins, growth factors, cytokines; from collagens, laminin, fibronectins, elastin, proteoglycans, or arginine-glycine-aspartic acid peptides. The implant further comprises cells on the surface; selected from smooth muscles cells, fibroblasts, urothelial cells, neutrophils, monocytes or macrophages.

Webster teaches a nano-structured implant comprising a polymeric material (col.2 line 49-57) with nano-sized surface features (col.4 line 39-50). The surface features have dimensions

of 1 – 100 nm (col.2 line 15-57); the polymeric material is polylactic acid (col.2 line 49-57), polyglycolides, polycaprolactones, and copolymers thereof (col.5 line 40-col.6 line 25). The implant may further comprise laminin, fibronectin, (col.7 line 20-34) and cells such as fibroblasts (examples).

The reference anticipates the claimed subject matter.

6. Claims 1 – 4, 6 – 7, 10 – 16 and 18 – 20 are rejected under 35 U.S.C. 102(e) as being anticipated by Hammerick et al. (US 2002/0173033 A1).

Applicant claims a nano-structured synthetic implant comprising a polymeric material having nano-sized surface features; wherein the features have one or more dimensions of 50nm – 1um; 100 nm – less about 1um; or 50 – 100 nm; or has a surface roughness of 50nm, 100nm or greater. The polymeric material is biodegradable; selected from poly (lactic acid – glycolic acid), polyetherurethane or polycaprolactone. The implant further comprises an extracellular matrix component; from bladder smooth muscle; from proteins, growth factors, cytokines; from collagens, laminin, fibronectins, elastin, proteoglycans, or arginine-glycine-aspartic acid peptides. The implant further comprises cells on the surface; selected from smooth muscles cells, fibroblasts, urothelial cells, neutrophils, monocytes or macrophages.

Hammerick teaches a device for implant (0004, 0026) comprising polylactic acid/polyglycolic acid copolymers (0083), wherein the substrate has wells on the surface in the nanometer range (0042), or has nano-sized surface features. Specifically the wells may be 0.1 micron (or 100 nanometers) or an indent (surface roughness of 50nm, 100nm or greater) (0042). The device may comprise layers of extracellular matrix molecules to include fibronectin (0100),

elastin or collagen (0083). Hammerick teaches the implant device may further be seeded with cells such as fibroblasts (0102).

The reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1 and 6 – 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Webster.

Applicant claims a nano-structured synthetic implant comprising a polymeric material having nano-sized surface features; wherein the surface roughness is 50nm or greater, 100 nm or greater; or wherein the surface area is greater than 30/25um^2.

Webster teaches a nano-structured implant comprising a polymeric material (col.2 line 49-57) with nano-sized surface features (col.4 line 39-50). The surface features have dimensions of 1 – 100 nm (col.2 line 15-57); surface roughness of 16 – 32 nm, and surface area of 1.07 – 1.73 um^2.

Webster does not teach the claimed surface roughness or area. However, the reference clearly teaches that these dimensions are greater compared to the average grain sizes and that the properties are due to the nano-sized structure (col.4 line 39-50). Webster teaches that the advantages are increased ductility and reduce brittleness (col.4 line 59-67). At the time of the claimed invention, one of ordinary skill in the art would have been motivated to optimize the specific surface roughness and area of the nano-implants of Webster for the disclosed advantages of ductility and reduced brittleness, with a reasonable expectation for successfully obtaining a nano-sized implant.

10. Claims 1, 5, 8 – 9 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hammerick.

Applicant claims a nano-structured synthetic implant comprising a polymeric material having nano-sized surface features; wherein the surface roughness is 25 - 50nm; has a surface area is greater than 30/25um^2; wherein the polymer is a film; or wherein collagen type IV is included.

Hammerick teaches a device for implant (0004, 0026) comprising polylactic acid/polyglycolic acid copolymers (0083), wherein the substrate has wells on the surface in the nanometer range (0042), or has nano-sized surface features. Specifically the wells may be 0.1 micron (or 100 nanometers) or an indent (surface roughness of 50nm, 100nm or greater) (0042). The device may comprise layers of extracellular matrix molecules to include fibronectin (0100), elastin or collagen (0083).

Hammerick does not teach the device wherein the claimed features are from 25 – 50 nm, wherein the surface area is 30/25um^2. However, the reference clearly teaches the device is designed to have nano-sized topology (or surface features) (0042). Thus, such parameters of the device are considered to be result effective. At the time of the claimed invention, one of ordinary skill in the art would have been motivated by Hammerick to optimize the surface features of the device within the claimed nano-sized ranges, since the reference expressly teaches and suggests to do so (0042). Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by Hammerick to optimize the surface features of the device to the claimed ranges with a reasonable expectation for successfully obtaining an effective nano-sized implant device.

Hammerick does not teach the device wherein the polymer is a film. However, Hammerick does teach a mask pattern wherein the pattern may be of a variety of shapes and types; and wherein the substrate is made from many layers of nano size (0062-0065), or are films. At the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to make the substrate of Hammerick with polymeric films, since the reference suggests using multiple nano-sized layers of polymeric substrate. Moreover, at the time of the claimed

invention, one of ordinary skill in the art would have been motivated by the teachings of Hammerick to use polymeric films as the substrate for the device with a reasonable expectation for obtaining an effective nano-sized implant device.

Hammerick does not teach the device comprising type IV collagen. However, the reference clearly teaches that collagen can be used as a subtrate material. At the time of the claimed invention, collagen type IV was a well known and used material in the art for implants. Thus, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by the disclosure of Hammerick and routine practice, to use collagen type IV in the device of Hammerick, with a reasonable expectation for successfully obtaining an effective nano-sized implant.

Double Patenting

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 1 – 12 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 7 – 20 of copending Application No. 10/362,148. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims encompass the more narrowly defined claims the the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

13. Claims 1 – 12 and 18 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 - 11 of copending Application No. 10/793,721. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are all drawn to a nano-sized substrate with similar and overlapping dimensions.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 571-272-0915. The examiner can normally be reached on M-F 7:00 -3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ruth A. Davis/
Primary Examiner
Art Unit 1651

May 24, 2007